advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Kytril™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Kytril™ is 1,996 days. Of this time, 1,371 days occurred during the testing phase of the regulatory review period, while 625 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* July 14, 1988. The applicant claims July 9, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 14, 1988, which was 30 days after FDA's receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* April 14, 1992. The applicant claims April 10, 1992, as the date the new drug application (NDA) for Kytril™ (NDA 20–239) was initially submitted. However, FDA records indicate that the NDA was initially submitted on April 14, 1992.

3. *The date the application was approved:* December 29, 1993. FDA has verified the applicant's claim that NDA 20–239 was approved on December 29, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 382 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 31, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 27, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 16, 1994.

**Stuart L. Nightingale,**

*Associate Commissioner for Health Affairs.*

[FR Doc. 94–21282 Filed 8–29–94; 8:45 am]

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**[Docket No. 94E–0104]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; Lipidil®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Lipidil® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Lipidil® (fenofibrate). Lipidil® is indicated as adjunctive therapy to diet for treatment of adult patients with very high elevations of serum triglyceride levels (Types IV and V hyperlipidemia) who are at risk of pancreatitis and who do not respond adequately to a determined dietary effort to control them. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lipidil® (U.S. Patent No. 4,739,101) from Fournier Innovation et Synergie, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 19, 1994, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Lipidil® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Lipidil® is 4,501 days. Of this time, 1,003 days occurred during the testing phase of the regulatory review period, while 3,498 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* September 6, 1981. The applicant claims August 16, 1981, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective

date was September 6, 1981, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: June 4, 1984. FDA has verified the applicant's claim that June 4, 1984, was the date the new drug application (NDA) for Lipidil® (NDA 19–304) was initially submitted.

3. *The date the application was approved*: December 31, 1993. FDA has verified the applicant's claim that NDA 19–304 was approved on December 31, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years and 256 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 31, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 27, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 16, 1994.

**Stuart L. Nightingale,**

*Associate Commissioner for Health Affairs.*

[FR Doc. 94–21285 Filed 8–29–94; 8:45 am]

BILLING CODE 4160–01–F

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**[Docket No. 94E–0070]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; Livostin®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Livostin® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Livostin® (levocabastine hydrochloride). Livostin® is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Livostin® (U.S. Patent No. 4,369,184) from Janssen Pharmaceutica N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 18, 1994, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Livostin® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Livostin® is 2,779 days. Of this time, 2,000 days occurred during the testing phase of the regulatory review period, while 779 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: April 4, 1986. The applicant claims April 5, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 4, 1986, which was 30 days after FDA's receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: September 24, 1991. The applicant claims September 20, 1991, as the date the new drug application (NDA) for Livostin® (NDA 20–219) was initially submitted. However, FDA records indicate that the NDA was submitted on September 24, 1991.

3. *The date the application was approved*: November 10, 1993. FDA has verified the applicant's claim that NDA 20–219 was approved on November 10, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,779 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 31, 1994, submit to